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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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21967 7590 12/08/2010 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109				
EXAMINER				
SANTOS, JOSEPH M				
ART UNIT		PAPER NUMBER		
3737				
MAIL DATE		DELIVERY MODE		
12/08/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/588,192

**Applicant(s)**

MEIRER ET AL.

**Examiner**

JOSEPH SANTOS

**Art Unit**

3737

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Specification***

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is unclear that the change made in the substitute specification was also an amendment to the title  
Appropriate correction is required.

***Claim Objections***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).
3. Misnumbered claims **33-55** been renumbered **34-56**.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims **34-56** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 34 and 46 set forth "a body wound area of at least one of a skin flap and skin graft", such a recitation implies that the wound could contain both a skin flap and a skin graft. The specification, as originally filed, fails to disclose having both a skin flap and a skin graft on the same wound. Therefore, such a recitation is considered to be new matter.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
- This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
7. Claims **34-37, 39-48, 50-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden et al. (US 6,390,995) in view of Sanctis et al. "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia", in view of Duarte (US 5,904,659).
- Ogden et al. disclose a therapeutic device and method used to generate shock waves medical treatment of a variety of pathological conditions associated with

bone environments and musculoskeletal environments, including the treatment of ischemic conditions such as bursitis. The method involves applying a sufficient number of acoustic shock waves to the site of a pathological condition including micro-disruptions, non-osseous tissue stimulation, increased vascularization, and circulation and induction of growth factors to induce or accelerate the body's natural healing processes and responses. In addition, the invention also relates to methods for using acoustic shock waves to treat damaged, scarred or unhealthy tissue. In addition, applying shock waves to stimulate formation of soft tissue morphogens and growth factors (see col. 3, lines 17-44). Ogden et al further teach the system may include a wide range in the various parameters used to treat all of the pathologies mentioned in this specification. Specifically, the number of pulses per treatment should be approximately 500-10,000 (see, col.6, lines 5-8). However Ogden fails to teach having impulses at an energy flux density of from  $0.05\text{mJ/mm}^2$  to  $0.2\text{mJ/mm}^2$ . In the same field of endeavor Sanctis discloses a shock wave applicator applied to the skin having pulses with an energy flux density of  $0.03\text{mJ/mm}^2$  to  $0.5\text{mJ/mm}^2$  (See Abstract). It would have been obvious to have modified Ogden to apply pulses with such a specific flux density in order to increase microcirculation. The modified Ogden fails to teach applying acoustic waves to specifically treat skin grafts. In the same field of endeavor Duarte discloses applying acoustic wave to treat wounds including skin grafts (see col. 1, lines 16-26). It would have been obvious to one skilled in the art to apply shock waves to such an area in order to treat the damaged tissue related to skin grafting and to further enhance growth factors to such areas. With respect to claims 37, 39, Ogden discloses applying focused shock waves (col. 3, lines 55-60). With respect to claims 40-46 and 53-56 the specific area in which the shock wave is to be applied would have been obvious depending on the specific size of the wound.

8. Claims **38 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogden et al. (US 6,390,995) in view of Sanctis et al. "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia", in view of Duarte (US 5,904,659), as applied to claims 37,46 above and in further view of Applicant's admission of record. Ogden discloses the systems and methods as disclosed above, but fails to specifically teach the shock waves include unfocused shock waves. However, in the applicant's specification is disclosed that the industry provides two main generation methods of extracorporeal shock waves focused and unfocused (see para. 0066, of applicant's specification). Therefore, having unfocused shock waves is well known expedient. It would have been obvious to have modified Ogden to have unfocused shock waves signals in order to treat the wound with a desired shock wave.

#### ***Response to Arguments***

9. Applicant's amendments to the claims and specification are sufficient to overcome the objection to specification and claims, the 35 USC 101 and the 35 USC 112, second paragraph rejections set forth in the previous office action.
10. Applicant's arguments filed 09/16/2010 have been fully considered but they are moot in view of new ground of rejection.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH SANTOS whose telephone number is 571-270-7782. The examiner can normally be reached on Monday through Friday 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRIAN CASLER can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.S./  
Examiner, Art Unit 3737

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737